

DATA MANAGEMENT PROBLEM STATEMENT

R&D's current electronic data management systems are inadequate to support the requirements of QTP.

PROBLEM:

- No uniform sample identification and sample tracking processes within R&D.
Central system for ID of sample
- No system to capture all records pertaining to the testing process, (QC data, calibration information, raw data, etc.).
- No means for transferring analytical data to a database, (for two QTP pilot laboratories).
- No centralized system for electronically storing, reporting, and retrieving data.

CONSEQUENCES:

- Therefore, the implementation of QTP within R&D will be difficult if not impossible.

ISSUES

- Traceability of method changes
- Standardized guidelines of QC for instruments
- Instruments not interfaced to network
- Automated vs. non-automated instruments
- No centralized sample tracking
- No central sample identification scheme
- No standard set of sample identifiers
- No object linking of results to memos, spreadsheets, statistical analyses
- Databases not integrated
- Paper trails for traceability
- Data accessibility
- Barcodes vs. worklists
- Dissimilar methods for data handling
- Transferability of data to analysts
- Capacity for long-term electronic storage of high volumes of data
- Internally developed instead of commercially developed software/database systems